

Appl. No. 10/525,544

Response to Final Office Action dated December 6, 2010

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	10/525,544)	
Applicant	:	William H. Simon)	MARCH 7, 2011
Filed	:	01/28/2005)	
)	
TC/A.U.	:	3775)	
Examiner	:	Michael J. Araj)	
Docket No.	:	Simon-1)	For: Method and apparatus for repairing
)	the mid-foot region via an intramedullary
Commissioner for Patents)	nail
Mail Stop: Amendment)	
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/Guerry Grune/

RESPONSE TO DECEMBER 6, 2010 FINAL OFFICE ACTION AND REQUEST FOR
CONTINUED EXAMINATION IN U.S. PATENT APPLICATION NO. 10/525,544

Dear Mr. Examiner;

This Amendment is being submitted in response to the December 6 Office Action in the above-identified application. Please amend the claims of the above-identified patent application as set out in Section I (Amendments to the Claims) hereof. Remarks concerning the amendments to the claims and the substance of the December 6, 2010 Office Action are set out in Section II (Remarks) hereof. In addition, as this is a response to a Final Rejection, applicant submits an RCE (Request for Continued Examination) with a payment of the \$405.00 small entity fee as specified in 37 CFR § 1.17(e) made by online credit card authorization at the time of EFS filing of this Response. Applicant requests that the examiner considers the response to the final office action in order to accelerate examination of the application.

Section II. Response to Objections

Claim 1 is objected to because of the following informalities: In claim 1, lines 12-13, "next into and through medial cuneiform bone", appears to be a typographical editing error. It appears that it should be 'next into and through said medial cuneiform bone'. Appropriate correction is required.

Applicant acknowledges the examiner's objections to claim 1 and has amended claim 1 to correct any improper wording. In addition, applicant has amended claim 1 to overcome the 35 USC 101, 35 USC 112 and 35 USC 103 rejections stated below. Specifically, claim 1 now reads as follows:

1. (Currently amended) A device for treatment or fixation of a fractured, damaged or deteriorating bone or set of bones in a mid-foot region, said midfoot region comprising the metatarsal bone, a medial cuneiform bone, a navicular bone and a talus bone, said device having a proximal end, a distal end, and a central cylindrical elongated wherein said proximal end is a chamfered end, and wherein said chamfered end is defined by a reduction in diameter by a 45 degree chamfer between said central cylindrical elongated body and said chamfered end, wherein a sufficient portion of said chamfered end is configured to reach a sufficient distance into said talus bone, wherein at least one proximal fastener hole is aligned with and lies along the same planar direction of said device within a navicular and a medial cuneiform portion of said midfoot region and at least one additional fastener hole that lies in a perpendicular direction to said device within a first metatarsal or talus bone portion of said midfoot region to fully secure said device with fasteners through any fastener hole and thereby securing said mid-foot region by providing support along an entire bored through medullary canal, said medullary canal extending along said mid-foot region such that said device is configured into and through said metatarsal bone, through said medial cuneiform bone, through said navicular bone and terminating into said talus bone.

Claim Rejections - 35 USC § 101

Claims 1 and 3-9 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 1, line 8, applicant positively recites part of a human, i.e. "inserted into said talus bone". Thus claims 1-9 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Applicant acknowledges the examiner's rejection of the amended claim 1 but applicant respectfully disagrees with the examiner's assertion that by positively reciting a portion of a human is the correct or proper interpretation of the claim. The claim(s) 1-9, are directed to a medical device which is used to assist a patient in recovering from the traumatic symptoms associated with Charcot syndrome. To describe the device it is necessary to describe how the device is positioned within the bones of the foot in order for one skilled in the art to practice the invention. As such, the 35 USC 101 rejection has no basis in fact as the applicant is simply describing locations where the device within a human would be located.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the metatarsal bone" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the cuneiform bone" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the navicular bone" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the talus bone" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the medullary canal" in line 10. There is insufficient antecedent basis for this limitation in the claim.

Applicant acknowledges the examiner's 35 USC 112 rejections regarding antecedent basis and has amended Claim 1 accordingly as shown above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schon et al. (U.S. Publication No. 2003/0097131).

Schon et al. disclose an intramedullary nail (4) having a proximal end, a distal end and a central cylindrical elongated body with a chamfered end and at least one slot (32) where said device comprises an attaching means to a bone. Said intramedullary nail is cannulated (see Figure 2) comprising a round cross-section with a central elongated body. The intramedullary nail is adapted with said attaching means by way of a proximal fastener hole (48) and a distal fastener hole (16) where a fastener (50) is inserted into at least one of the fastener holes. Said fastener is configured and dimensioned for insertion in at least one of said fastener holes, further comprising a threaded hole for insertion of a screw.

With regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Schon et al. which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458,459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Additionally, it would have been an obvious matter of design choice to have created the nail to be of a smaller size to fit a human foot versus an elephant's foot, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Schon et al. disclose the claimed limitations except for the chamfered end being defined by a reduction in diameter by a 45 degree chamfer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have created the device of Schon et al. by a 45 degree chamfer, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Applicant acknowledges the examiner's 35 USC 103(a) rejection and respectfully disagrees with the examiner's assertion that Schon, et. al. anticipate, suggests, or motivates one skilled in the art to develop the claimed invention. Intramedullary screws with chamfered ends for use in the mid-foot region to alleviate Charcot syndrome were never contemplated by anyone with a medical background in the history of medicine as can be attested to by any podiatrist. The conventional method of treating the Charcot foot issues, has been to support the mid-foot region with horizontal braces that often, in use, cause great injury and ill-repair to the patient. regarding antecedent basis and has amended Claim 1 accordingly. Additionally, it is suggested to clarify the medullary canal to which the applicant states in claim 1. It is encouraged that the applicant calls the examiner to expedite the prosecution of this case. Schon, et. al., may show a similar

structure, but the structure shown is neither capable, anticipated, or suggestive of the present invention.

As suggested by the examiner, applicant has added verbiage in claim 1 to clarify the medullary canal issues, the distinction of providing a device for the mid-foot region and to distinguish the claim language from the cited art.

Applicant submits that the application is now in condition for allowance, and early notification of such action is earnestly solicited.

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Dated this 7th day of March 2011

Respectfully Submitted,

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